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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,706	10/06/2003	Lutz Biedermann	B884:56603	2637

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EXAMINER	
WOODALL, NICHOLAS W	

ART UNIT	PAPER NUMBER
3733	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/680,706	BIEDERMANN ET AL.	
	Examiner	**Art Unit**	
	Nicholas Woodall	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _30 November 2007_.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1,3-5,7,8,10-23,27 and 32-42_ is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) _1,3-5,7,8,10-23,27 and 32-42_ is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on _30 November 2007_ is/are: a)☐ accepted or b)☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☒ All b)☐ Some * c)☐ None of:
1.☒ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _11/30/2007_.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 11/30/2007.

Drawings

2. The drawings were received on 11/30/2007. These drawings are not acceptable for the reasons below.

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first internal thread extending over the entire length of the thread section (claim 11) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

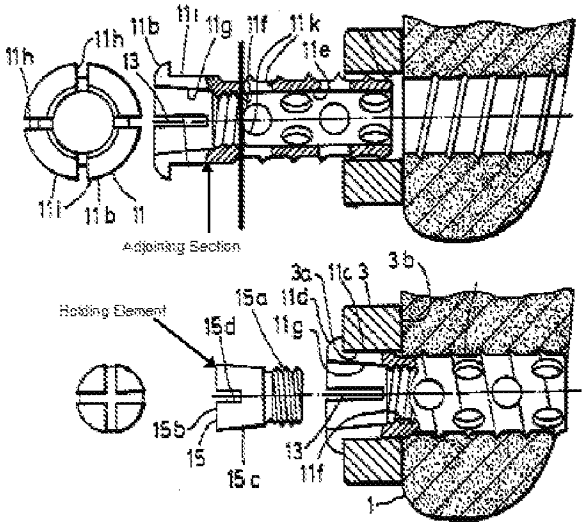
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 5, 7, 8, 10, 12, 13, 17, 18, 20, 22, 32, 33, 35, 37, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) and Kambin (U.S. Patent 5,964,761).

Regarding claim 1, Sutter discloses a device comprising a thread section of elongated tubular construction (11) capable of being implanted in a living body having an outer wall, a first end, and a second end (see Figure 1 below). The tubular thread section further comprises a bone thread on the outer wall and a plurality of recesses forming a mesh-like open network. The device further comprises a holding mechanism including a screw shaped insert (15) connected to the thread section at the second end in order to hold the elongated tubular thread section to a bone plate. Sutter fails to disclose the device further comprising a tip at the first end of the thread section and the holding mechanism further including an elongated element further comprising a stop. Ballantyne teaches a device comprising an elongated tubular thread section further comprising a tip at the first end of the thread section capable of being removed from the thread section in order to self tap and guide the thread section during insertion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Sutton further comprising a tip in view of Ballantyne in order to self tap and guide a thread section during insertion. Kambin teaches a device further comprising a holding mechanism including an elongated element connected to the second end of a tubular section comprising a first section, an elongated rod-like section, and a stop configured as an annular projection fixedly provided on the holding element capable of preventing further penetration of the holding element into a elongated tubular section in order to hold an elongated tubular section to a bone plate (see Figure 2 below). Because both Sutter and Kambin teach devices comprising holding mechanisms, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one holding mechanism for the other in order to achieve the predictable results of holding an elongated tubular section to a bone plate.

Regarding claim 3, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the thread section further comprising a first internal thread section at its second end and the first section of the holding element comprises an external thread capable of cooperating with the first internal thread section. Regarding claim 5, the combination of Sutton, Ballantyne, and Kambin disclose a device further comprising an engagement element at the free end of the holding element capable of cooperating with a screw-in tool. Regarding claim 7, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the stop comprises a shoulder. Regarding claim 8, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the thread section further comprises a stop located on the inside of the outer wall capable of preventing further penetration of the holding element into the thread section. Regarding claim 10, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the thread section further comprises a second internal thread section at the first end. Regarding claim 12, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the first internal thread section comprises a metric or inch thread. Regarding claim 13, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the tip is structured as a self-tapping tip. Regarding claim 17, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the thread section comprises an adjoining section at the second end free of bone screw thread having a second length, wherein the section free of the thread is less than or equal to the diameter of the thread section. Regarding claim 18, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the engagement element comprises an internal thread section at the second end capable of cooperating with a screw-in tool. Regarding claim 20, the combination of Sutton, Ballantyne, and Kambin disclose a device wherein the engagement element comprises an internal thread section at the second end, and the device further comprises a fixation element that cooperated with the engagement element capable of fixing the device. Regarding claim 22, the combination of Sutton, Ballantyne, and Kambin disclose a device as discussed above further comprising a bone plate and a nut, wherein the bone plate includes a recess capable of receiving the second end of the device can be passed through and wherein the nut is capable of cooperating with the second end to fix the bone plate. Regarding claims 32, 33, and 35, the combination of Sutton, Ballantyne, and Kambin disclose a device as discussed above. Regarding claim 37, the combination of Sutton, Ballantyne, and Kambin disclose a device inherently capable of being used by a method comprising the steps of connecting an elongated holding element to a thread section at a second end of the thread section, the thread section having an outer wall including a first end, the second end, and a tip at the first end, the thread section further comprising a bone thread on the outer wall and the outer wall further comprising a plurality of recess, the holding element comprising a first section for connection to the second end of the thread section and an elongated rod-like second section having a longitudinal length and a free end opposite the first section, the elongated holding element having a stop configured as an annular projection fixedly provided on the holding element and located between the first section and the second section, and screwing the thread section into the bone, wherein at least a portion of the holding element is immersed into the bone, wherein connecting the holding element to the thread section comprises inserting the first section of the holding element into the second end of the thread section until the stop of the holding element engages at least a portion of the second end of the thread section to prevent further insertion of the first section of the holding element into the second end of the thread section. Regarding claim 40, the combination of Sutton, Ballantyne, and Kambin disclose a device inherently capable of being used by a method as discussed above wherein connecting the holding element to the thread section comprises screwing a threaded portion of the first section of the holding element into a threaded inner portion of the second end of the thread section. Regarding claim 42, the combination of Sutton, Ballantyne, and Kambin disclose a device inherently capable of being used by a method as discussed above further comprising removing the holding element after the thread section is immersed into the bone.

Figure 1



6. Claims 4, 34, 36, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) further in view of Kambin (U.S. Patent 5,964,761) further in view of Tronzo (U.S. Patent 4,940,467).

Regarding claims 4, 34, and 36, the combination of Sutter, Ballantyne, and Kambin disclose the invention as claimed except for the holding element and the threaded section being connected by press-fit connections. The combination of Sutter, Ballantyne, and Kambin disclose a device comprising a holding element comprises a threaded connector in order to connect the holding element to a second element of the device. Tronzo teaches a device comprising a holding element comprising a press-fit connector in order to connect the holding element to a second element of the device. Because both the combination of Sutter, Ballantyne, and Kambin and Tronzo teach devices comprising connectors between a holding element and a second element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one connector for the other in order to achieve the predictable results of connecting a holding element to a second element.

Regarding claim 41, the combination of Sutter, Ballantyne, Kambin, and Tronzo disclose a device inherently capable of being used by a method as discussed above wherein connecting the holding element to the thread section comprises press fitting the first section of the holding element into the second end of the thread section.

7. Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) further in view of Kambin (U.S. Patent 5,964,761) further in view of Tronzo (U.S. Patent 4,940,467) further in view of Boothroyd (Product Design For Manufacture and Assembly).

Regarding claims 11 and 21, the combination of Sutter, Ballantyne, Kambin, and Tronzo disclose the invention as claimed except for the first thread section extending over the entire length of the thread section and the second length of the adjoining section being the same as or greater than the first length of the bone thread section. Boothroyd teaches that designing the elements of a device to be symmetrical increase the ease of assembly and lowers assembly time overall (pages 64 and 77). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Sutter, Ballantyne, Kambin, and Tronzo wherein the first thread section extends over the entire length of the thread section and wherein the second length of the adjoining section is the same as the first length of the bone thread section in order to make the elements of the combination more symmetrical to ease the assembly and lower the assembly time of the device.

8. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) further in view of Kambin (U.S. Patent 5,964,761) further in view of Moore (U.S. Patent 6,402,757).

Regarding claims 14-16, the combination of Sutter, Ballantyne, and Kambin disclose the invention as claimed except for the device further comprising a cannula extending through the entire device. Moore teaches a device further comprising a cannula extending through the entire device in order to allow use of a guide wire during installation of the device. It would have been obvious to one having skill in the art at the time the invention was made to manufacture the combination of Sutter, Ballantyne, and Kambin further comprising a cannula extending through the entire device in view of Moore in order to allow use of a guide wire during installation of the device.

9. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) further in view of Kambin (U.S. Patent 5,964,761) further in view of Moore (U.S. Patent 6,402,757) further in view of Tronzo (U.S. 4,940,467).

Regarding claim 27, the combination of Sutter, Ballantyne, Kambin, and Moore disclose the invention as claimed except for the holding element and the threaded section being connected by press-fit connections. The combination of Sutter, Ballantyne, Kambin, and Moore disclose a device comprising a holding element comprises a threaded connector in order to connect the holding element to a second element of the device. Tronzo teaches a device comprising a holding element comprising a press-fit connector in order to connect the holding element to a second element of the device. Because both the combination of Sutter, Ballantyne, Kambin, and Moore and Tronzo teach devices comprising connectors between a holding element and a second element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one connector for the other in order to achieve the predictable results of connecting a holding element to a second element.

10. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. Patent 4,022,099) further in view of Kambin (U.S. Patent 5,964,761) further in view of Moore (U.S. Patent 6,053,916).

Regarding claim 38, the combination of Sutter, Ballantyne, and Kambin disclose a device inherently capable of being used by a method as discussed above except for the method further comprising filling the thread section with bone material. Moore teaches a method comprising the step of filling a thread section with bone material in order to facilitate fusion of the device and bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Sutter, Ballantyne, and Kambin further comprising the step of filling the thread section with bone material in view of Moore in order to facilitate fusion of the device and bone.

Regarding claim 39, the combination of Sutter, Ballantyne, Kambin, and Moore disclose a device inherently capable of being used by a method as discussed above wherein the filling the thread section with bone material occurs before connecting the holding element to the thread section.

11. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tipirrneni (U.S. Publication 2004/0172030) in view of Sutter (U.S. Patent 4,484,570).

Regarding claim 1, Tipirrneni discloses a device comprising a thread section (6 and 8) of elongated tubular construction, a tip (4) at a first end of the thread section, and an elongated holding element (12). The thread section includes an outer wall, a first end, and a second end, wherein the outer wall further includes a bone thread. The elongated holding element includes a stop configured as an annular projection and an outer diameter that is less than the outer diameter of the thread section, wherein the device is capable of being fully immersed in an opening created when screwing the device into bone. Tipirrneni fails to disclose the device wherein the outer wall of the thread section includes a plurality of recesses. Sutter teaches a device comprising an outer wall further comprising a plurality of recesses in order to facilitate fusion between the device and bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Tipirrneni further comprising a plurality of recesses on the outer wall in view of Sutter in order to facilitate fusion between the device and bone.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tipirrneni (U.S. Publication 2004/0172030) in view of Sutter (U.S. Patent 4,484,570) further in view of Klaue (U.S. Patent 4,705,027).

Regarding claim 23, the combination of Tipirrneni and Sutter fail to disclose the device further comprising a marrow nail, i.e. an intramedullary nail. The combination of Tipirrneni and Sutter disclose a device capable of being used with a bone fixation element, such as a bone plate, to facilitate the fixation of bone fractures. Klaue teaches a device comprising a bone fixation element, i.e. intramedullary nail, capable of being used with bone anchors in order to facilitate the fixation of bone fractures. Because both the combination of Tipirrneni and Sutter and Klaue teach devices comprising bone fixation elements, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one bone fixation element with the other one in order to achieve the predictable results of facilitating the fixation of bone fractures.

13. Claims 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. 4,022,099).

Regarding claim 17, Sutter discloses a device comprising a thread section capable of being implanted into a living body comprising a one-piece elongated tubular construction with an outer wall, a first open end extending through the elongated tubular construction to a second open end, wherein the outer wall contains a plurality of recesses forming a mesh-like open network, a bone thread, and an adjoining section free of bone threads, wherein the diameter of the adjoining section is less than or equal to the diameter of the thread section (see Figure 2 below). The device further comprises an engagement element at the second open end capable of cooperating with a screw-in tool. Sutter fails to disclose the device further comprising a tip capable of being connected to the first end of the thread section. Ballantyne teaches a device comprising a removable tip connected to a thread section of the device in order to self tap and guide a thread section during insertion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Sutter further comprising a tip in view of Ballantyne in order to self tap and guide a thread section during insertion.

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sutter (U.S. Patent 4,484,570) in view of Ballantyne (U.S. 4,022,099) further in view of Boothroyd (Product Design For Manufacture and Assembly).

Regarding claim 21, the combination of Sutter and Ballantyne disclose the invention as claimed except for the second length of the adjoining section being the same as or greater than the first length of the bone thread section. Boothroyd teaches that designing the elements of a device to be symmetrical increase the ease of assembly and lowers assembly time overall (pages 64 and 77). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the combination of Sutter and Ballantyne wherein the second length of the adjoining section is the same as the first length of the bone thread section in order to make the elements of the combination more symmetrical to ease the assembly and lower the assembly time of the device.

Response to Arguments

15. Applicant's arguments with respect to claims 1, 3, 4, 5, 7, 8, 10-23, 27, and 32-42 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3733

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733